

**UNITED STATES DISTRICT COURT FOR THE
MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION**

ABBVIE INC., *et al.*,

Plaintiffs,

v.

JONATHAN SKRMETTI, *in his official
capacity as* TENNESSEE ATTORNEY
GENERAL,

Defendant.

Case No. 3:25-cv-519
District Judge Aleta A. Trauger

**REPLY IN SUPPORT OF
GENERAL SKRMETTI'S MOTION TO DISMISS**

ARGUMENT*

AbbVie asks for discovery to prove the Hospital Protection Act “will not . . . benefit the public.” Mot. Dismiss Resp., D.52 at 2066. But this is not a Court of policy; this is a Court of law. AbbVie has failed to state a viable claim to relief.

First, AbbVie insists on litigating hypotheticals. The Courts in this Circuit provide “party-specific and injury-focused” remedies. *L. W. ex rel. Williams v. Skrmetti*, 83 F.4th 460, 490 (6th Cir. 2023). In this case, that can only mean an order protecting AbbVie from a “certainly impending” unlawful prosecution by General Skrmetti. *Christian Healthcare Ctrs., Inc. v. Nessel*, 117 F.4th 826, 843 (6th Cir. 2024) (quoting *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 158 (2014)). But AbbVie refuses to identify the “concrete context” out of which such “an enforcement action” would arise. *Ammex, Inc. v. Cox*, 351 F.3d 697, 706–07 (6th Cir. 2003). The closest it comes is saying it seeks certain “claims data” from a handful of unnamed 340B Hospitals. Mot. Dismiss Resp., D.52 at 2072 (quoting Compl., D.1 at 30); *see also id.* (citing *AbbVie, Inc. v. Skrmetti*, --- F. Supp. 3d ---, 2025 WL 1805271, at *9–10 (M.D. Tenn. 2025)).

If those Hospitals are in Tennessee, why does AbbVie refuse to identify them? And if AbbVie’s grievance is about claims data, why has it sought to enjoin General Skrmetti “from enforcing [the Hospital Protection Act]” full stop? Compl., D.1 at 73. This is no “exaggeration.” Mot. Dismiss Resp., D.52 at 2073. Those are the words AbbVie used in its complaint. *See* Compl., D.1 at 72–73. Regardless, AbbVie now admits it has *at most* put only the claims-data “provision” of the Hospital Protection Act at issue. *Tex. All. for Retired Ams. v. Scott*, 28 F.4th 669, 672 (5th Cir. 2022) (quoting *Tex. Democratic Party v. Abbott*, 978 F.3d 168, 179 (5th Cir. 2020)); *see* Mot. Dismiss Resp., D.52 at 2072–73 (focusing on Hosp. Prot. Act § 1(a)(1), D.23-1 at 837).

* Pincites to docket entries use the Page ID file-stamp pagination.

Second, AbbVie stakes its obstacle preemption claim on statutory innuendo, an inflated sense of self, and a rejection of federalism. See Mot. Dismiss Resp., D.52 at 2073–76.

If Congress had wanted 340B Hospitals “to provide claims data to manufacturers,” it could have easily said so. *Id.* at 2075. Yet AbbVie admits “that no rule in the 340B Program has ever” entitled manufacturers to such information. *Id.* This necessarily means that there is no clear statutory language preempting the Hospital Protection Act’s claims-data provision. *See Will v. Mich. Dep’t of State Police*, 491 U.S. 58, 65 (1989). And it shows that drugmakers do *not* need to pry such information “[in]voluntarily” from 340B Hospitals to accomplish Congress’s goals. *Mot. Dismiss Resp., D.52 at 2075* (citing *Compl., D.1 at 52*). Instead, drug manufacturers can purchase claims data from those willing “providers and dispensers” who “are already generating” it as a “routine business practice.” *Id.* Or they can trust the federal regulators who have independent power to investigate “potential diversion[s] or duplicate discounting.” *Id.* at 2074 (citing *Compl., D.1 at 37, 52*); *see* 42 U.S.C. § 256b(a)(5)(A)(ii), (C), (D).

Indeed, AbbVie admits that “Congress provided specific [340B] enforcement tools” to the federal executive branch. *Mot. Dismiss Resp., D.52 at 2074; see id. at 2067.* Nevertheless, AbbVie sees itself as responsible for “bring[ing]” those regulators “to action” and “holding [them] accountable to [their] statutory obligations.” *Id.* at 2074–75. But while AbbVie might want to oversee the U.S. Department of Health and Human Services, Congress arranged things the other way around. 42 U.S.C. § 256b(a)(5)(C)–(D). And if ever Congress thought the Department were performing inadequately, it could rewrite the law to give manufacturers the investigatory tools — and exemptions from state law — that AbbVie claims to already have.

Yet even in that alternate world where the 340B statute’s text could support a preemption claim, the claim would gain nothing from AbbVie’s separate concern over litigating “questions

about the [340B] statute in[] a state forum.” Mot. Dismiss Resp., D.52 at 2076. Preemption flows from the Supremacy Clause, which does no more than “create[] a rule of decision.” *Armstrong v. Exceptional Child Ctr., Inc.*, 575 U.S. 320, 324 (2015). So Tennessee’s courts apply “the Laws of the United States” every day; the Constitution “b[i]nd[s]” them to do so. U.S. Const. art. VI. It is also their province to fix the meaning of every term in the Hospital Protection Act. *See* Tenn. Const. art. VI, § 1; *Johnson v. Fankell*, 520 U.S. 911, 916 (1997). This is not some novel arrangement susceptible to preemption. This is the way federalism works.

Third, AbbVie’s primary “field preemption” argument has nothing to do with “field preemption” doctrine. AbbVie no longer describes the sale of 340B drugs as an exclusively federal regulatory “field.” *Compare* Mot. Dismiss, D.47 at 1911–12, *with* Mot. Dismiss Resp., D.52 at 2076–77, 2082. Instead, AbbVie now principally claims “field preemption” based on Tennessee’s “eliminat[ion]” of a specific and narrow “liberty” supposedly granted (through silence) by Congress. Mot. Dismiss Resp., D.52 at 2076. It is anyone’s guess what this new theory has to do with field preemption. *See* Mot. Dismiss, D.47 at 1911. But regardless, the “liberty” to “prescribe the . . . non-price terms” of a drug sale derives from State — not federal — law. Mot. Dismiss Resp., D.52 at 2076; *see* Mot. Dismiss, D.47 at 1911–12.

Fourth, AbbVie’s Due Process claim relies on an interpretation of the Hospital Protection Act that the Tennessee courts would not endorse. Having narrowed the focus of this claim to the statute’s “catch-all” provision, AbbVie insists it “vests” the Attorney General with “unbounded discretion” to impose liability. Mot. Dismiss Resp., D.52 at 2078 (addressing Hosp. Prot. Act § 1(a)(6), D.23-1 at 837). But Tennessee’s courts would not view this as the “flatly” unconstitutional consolidation of power that AbbVie apparently wants it to be. *Id.*; *see Willeford v. Klepper*, 597 S.W.3d 454, 465 (Tenn. 2020). Instead, they will see it as outlawing forms of

“interfere[nce]” with the 340B discount not specifically enumerated in the statute. Hosp. Prot. Act § 1(a)(6), D.23-1 at 837. And so construed, this provision provides constitutionally sufficient notice of what conduct is proscribed. *See AbbVie*, 2025 WL 1805271, at *21.

Fifth, despite narrowing its First Amendment claim, AbbVie still grossly overstates its federal rights. AbbVie has abandoned any argument that the Hospital Protection Act “targets ‘speech as speech.’” *McLemore v. Gumucio (McLemore II)*, --- F.4th ----, 2025 WL 2319119, at *3 (6th Cir. 2025); *see* Mot. Dismiss Resp., D.52 at 2078–79. But AbbVie doubles down on a Petition Clause theory that has no basis in law. *See AbbVie*, 2025 WL 1805271, at *24–25. The Hospital Protection Act does not “prevent[] AbbVie from accessing the federal ADR system.” Mot. Dismiss Resp., D.52 at 2079; *see AbbVie*, 2025 WL 1805271, at *15–16. And AbbVie cites no Petition Clause precedent even remotely analogous to the situation before the Court in this case. *See* Mot. Dismiss Resp., D.52 at 2079 (relying only on cases “about retaliation against government employees and contractors” for their political activity, Prelim. Inj. Resp., D.23 at 829).

Sixth, although there never was “a live question” about “AbbVie’s contract-pharmacy limitation,” Mot. Dismiss Resp., D.52 at 2080; see Prelim. Inj. Resp., D.23 at 812–16; see supra at 1, AbbVie’s additional constitutional claims could not justify discovery.

The Hospital Protection Act does not “compel[]” AbbVie to do anything, much less “transfer its drugs at discounted prices to private third parties.” Mot. Dismiss Resp., D.52 at 2080. Discovery is not needed to “clarif[y]” the legal rules of the 340B Program. *Id.* at 2081. And under those rules, AbbVie must *sell* discounted drugs to 340B Hospitals if AbbVie *wants* to do business with the federal government. *See* 42 U.S.C. § 256b(a)(1). Federal law then permits *those Hospitals* to request that drugs be delivered to contract pharmacies for dispensing on the Hospitals’ “behalf.” Hosp. Prot. Act, D.23-1 at 838; *see PhRMA v. McClain*, 95 F.4th 1136, 1142 (8th Cir.

2024). Meanwhile, Tennessee’s police power provides the countless background rules of property and contract that allow these transactions to happen. *See* Mot. Dismiss, D.47 at 1910. The fact that AbbVie does not *like* one of those laws does not turn the whole transaction into a taking. *See Slaybaugh v. Rutherford Cnty.*, 114 F.4th 593, 598 (6th Cir. 2024); *Tenn. Scrap Recyclers Ass’n v. Bredesen*, 556 F.3d 442, 453–56 (6th Cir. 2009). This is at the core of the “many problems” with AbbVie’s hand-wave-reliant Takings Clause claim. *AbbVie*, 2025 WL 1805271, at *19.

AbbVie’s return to the concept of “field preemption” fares no better. AbbVie now claims there is a “field of 340B pricing” that Congress exclusively controls. Mot. Dismiss Resp., D.52 at 2082. But even if the 340B ceiling price were (somehow) a regulatory field, it would still not preempt the Hospital Protection Act. This is because the Hospital Protection Act concerns itself with the “[non-]price term[s] for drug sales to” 340B Hospitals. *Sanofi Aventis U.S. LLC v. HHS*, 58 F.4th 696, 704 (3d Cir. 2023). And that is something state law has always governed, and federal law has always ignored. *See* 42 U.S.C. § 256b(a)(1); *see supra* at 3.

Finally, AbbVie’s Dormant Commerce Clause claim has no leg to stand on following *National Pork Producers Council v. Ross*, 598 U.S. 356 (2023). The facts and analysis in *Ross* show that the doctrine pertains only to discrimination between in-state firms and out-of-state firms within “the same industry.” Mot. Dismiss Resp., D.52 at 2084 (quoting *Novartis Pharms. Corp. v. Bailey*, 2025 WL 489881, at *5 (W.D. Mo. Feb. 13, 2025)). Indeed, “California imports almost all the pork it consumes,” but that did not pose a problem for its pork-production laws in *Ross*. 598 U.S. at 367. Several federal circuit courts have recognized this and applied *Ross*’s nondiscrimination rule accordingly. *See* Mot. Dismiss, D.47 at 1917–19 (citing *Flynt v. Bonta*, 131 F.4th 918 (9th Cir. 2025); *N.J. Staffing All. v. Fais*, 110 F.4th 201 (3d Cir. 2024)).

CONCLUSION

This Court should dismiss AbbVie’s complaint with prejudice.

Dated: August 28, 2025

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that I filed the above document using the Court's CM/ECF system on August 28, 2025, which electronically served a copy to all counsel of record::

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